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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,572	05/14/2004	Itzhak Bentwich	050992.0202.01USCP	3571

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EXAMINER	
WOLLENBERGER, LOUIS V	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/709,572	BENTWICH ET AL.	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008 and 02 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26,29,30 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26,29,30 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 May 2004 and 30 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions/Status

In the reply filed 2/25/08, Applicant elected, without traverse, SEQ ID NO:159.

Applicant's amendment to claim 30, deleting references to all previously recited SEQ ID NOs except SEQ ID NO:6821380 is considered to represent constructive election of SEQ ID NO:6821380.

Claims 25, 26, 29, 30, and 35-38 are pending and examined herein.

Oath/Declaration

The Declaration under 37 CFR 1.63 submitted 5/14/2004 is objected to because the final page containing the signatures and relevant information corresponding to said signatures is illegible. It cannot be clearly determined which signature corresponds to which inventor. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Also acknowledged is applicant's claim for foreign priority based on a PCT application PCT/IL03/00998 filed in the Israel on 11/26/2003. See Application Data Sheet filed 5/14/04. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Notwithstanding the absence of a certified copy, Applicant's priority claims are somewhat confusing. For example, while the Application data sheet sets forth in clear concise terms those US Provisional and Non-Provisional Applications to which benefit is claimed, the first 16 pages of the specification recites a lengthy and seemingly repetitive list of related applications, many of which are not listed on the Application Data Sheet or the Oath/Declaration. For example, Application 10/310914, filed 12/6/02, and 60/468251, filed 5/7/03, is listed in the Cross-Reference section of the specification.

Additionally, the Foreign Priority document PCT/IL03/00998, published as WO 2004/048511, itself claims priority to several US Provisional and Non-Provisional cases. Accordingly, it would appear that the instant case should be listed as continuation or CIP of PCT/IL03/00998. Clarification is requested.

Further with regard to priority, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications to which priority is claimed (see completed list below) fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 claims 25, 26, 29, 30, and 35-38 of this application. In particular support is not found therein for SEQ ID NO:159 or 6821380.

Accordingly, for purposes of this examination the earliest effective filing date is considered to be that of the instant application: 5/14/2004.

Continuing Data:

This is a Continuation-in-part of US application number 10/707975, filed 2004-01-29 , now PENDING.

This is a Continuation-in-part of US application number 10/707980, filed 2004-01-29 , now PENDING.

This is a Continuation-in-part of US application number 10/707147, filed 2003-11-24 , now PENDING.

This is a Continuation-in-part of US application number 10/604985, filed 2003-08-29 , now PENDING.

This is a Continuation-in-part of US application number 10/651227, filed 2003-08-29 , now PENDING.

This is a Continuation-in-part of US application number 10/649653, filed 2003-08-28 , now PENDING.

This is a Continuation-in-part of US application number 10/604926, filed 2003-08-27 , now PENDING.

This is a Continuation-in-part of US application number 10/604726, filed 2003-08-13 , now PENDING.

This is a Continuation-in-part of US application number 10/604727, filed 2003-08-13 , now PENDING.

This is a Continuation-in-part of US application number 10/708204, filed 2004-02-16 , now PENDING.

This is a Continuation-in-part of US application number 10/708953, filed 2004-04-02 , now PENDING.

This is a Continuation-in-part of US application number 60/521,433, filed 2004-04-26 , now PENDING.

Claim Rejections - 35 USC § 101 and 112, First Paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26, 29, 30, and 35-38 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility, or a well established utility.

In one embodiment, the claims are drawn to an isolated nucleic acid sequence of 19 to 24 nucleotides comprising a) at least 19 consecutive nucleotides of SEQ ID NO:159; b) an RNA equivalent of (a); c) a sequence at least 80/% identical to (a) or (b); or d) the complement of any one of (a)-(c).

In other embodiments the claims are drawn to an isolated nucleic acid sequence of 50 to 140 nucleotides comprising a) at least 19 consecutive nucleotides of SEQ ID NO:159; b) an RNA equivalent of (a); c) a sequence at least 80/% identical to (a) or (b); or d) the complement of any one of (a)-(c).

In still another embodiment, the claims are drawn to a nucleic acid 50 to 140 nucleotides comprising SEQ ID NO:6821380.

SEQ ID NO:159 is a 22-mer contained within SEQ ID NO:6821380, an 87-mer. For reference, each sequence is reproduced below.

SEQ ID NO: 159: acaaagcgcttctctttagagt

SEQ ID NO: 6821380:

tctcatgctgtgactctctggagggaagcactttctgttgtctgaaagaaaacaaagcgcttctctttagagtgttac ggtttgaga

Thus, as taught by the specification, the claims are drawn to preprocessed hairpin and mature miRNA (microRNA) sequences. Also claimed are vectors thereof.

At the outset, it is noted that the instant application is extremely large, comprising a 245-page specification, and at least 14 different mega tables, disclosing millions if not 10s of millions of different nucleic acid sequences, said to be precursor and processed miRNAs, with homologies to countless numbers of different targets, and having a wide variety of asserted utilities based on that homology(see paragraph 24 of the specification).

Information describing the particular features, function, use, and/or advantages of SEQ ID NO: 159 or 6821380 is not readily found in the specification as filed. While in the reply filed 2//25/08, Applicant points to Tables 1 and 2 for support for amendments to the claims, written description support is not readily found therein describing and teaching methods for using the instantly claimed nucleic acids for any purpose. Moreover, a search of the prior art for the instant sequences fails to find any identical, substantially similar , or substantially complementary sequences that might reasonably show a well-established utility for the claimed nucleic acids. Accordingly, the Examiner fails to find information particular to the invention claimed. Additionally, there are no working examples in the disclosure as filed showing or demonstrating the use of the claimed invention for any particular purposes. As a result, currently there is no evidence of any specific or substantial utility. No gene target is described, or readily found upon review of the application.

Furthermore, while the specification and prior art teach that putative miRNAs have been shown to inhibit protein translation or at least gene expression, the instant miRNA is but one of millions of candidate miRNAs disclosed and bioinformatically predicted by Applicant, for

which the presumed utility depends entirely on the accuracy and reliability of the algorithm used to identify preprocessed and mature miRNAs. Based on the evidence available in the pre- and post-filing art describing the difficulties and potential pitfalls of miRNA bioinformatic prediction programs in general, there is reason to doubt the objective truth of the assertions in the specification generally alleging that each of the bioinformatically predicted miRNAs disclosed therein may be used to inhibit gene expression. Thus, there is reason to doubt the credibility of the asserted utility.

A "specific utility" is *specific* to the subject matter claimed >and can "provide a well-defined and particular benefit to the public." *In re Fisher*, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005)<. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

To satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." Thus a< "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230.

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope (MPEP 2107.02).

The following findings are pertinent.

1. The specification teaches that Micro RNAs (miRNAs), are short ~22nt non-coding regulatory RNA oligonucleotides, found in a wide range of species, believed to function as specific gene translation repressors, sometimes involved in cell-differentiation.

2. The specification teaches a bioinformatic method for detecting putative miRNA-like precursor sequences in the genome of an organism. Further bioinformatics processing is then used to predict the single stranded miRNAs likely produced from such sequences, as by enzymatic cleavage of the sequence in the cell. Finally, the sequences of the predicted mature miRNAs are compared to sequences of known genes to identify potential targets and possible biological functions of the miRNAs.

3. While the specification teaches miRNA prediction, support is not readily found showing that the claimed miRNAs are actually produced in any cell or organism, or even if produced artificially, would lead to any biological effect of any immediate, real world value. No biologically relevant data is found in the instant application confirming any of the asserted utilities. Indeed, the asserted utility and target gene of this and thousands of other miRNA-like sequences appears to be based purely on bioinformatic methods for predicting RNA folding and potential gene targets.

4. Pre- and Post-filing art indicates that while prediction software and bioinformatics methods significantly narrow the field of possible sequences, they do not substitute for or render unnecessary the need for biological validation.

a. Krutzfeldt et al. (2006) *Nature Genetics* 38:514-519 state that, in general, the basis for these types of prediction programs is the degree of sequence complementarity between a miRNA and a target UTR, including the presence of a consecutive string of base pairs at the 5′ end of the miRNA known as a 'seed' or 'nucleus', and the cross-species conservation of this binding site. On average, 200 genes are predicted to be regulated by a single miRNA. The authors further state that reviewing the data provided by these algorithms determining candidate targets uncovers the entire gamut of gene categories, such as transcription factors, protein kinases, vesicular trafficking molecules and membrane receptors, suggesting that there is no apparent bias towards one particular function. Thus, multiple targets are possible.

b. Bentwich (2005) *FEBS Lett.* 5904-5910 teaches that biological validation is necessary to raise the specificity and sensitivity of microRNA prediction algorithms, implying that predictions based on such algorithms need validation and that prediction does not guarantee that such a sequence exists or has the function assigned to it by the software.

c. In general, miRNA prediction algorithms used in the art are said to have false positive rates of between 22% and 39%. See Bentwich et al. (2005) *FEBS Lett.* 579:5904-5910, page 5907; and Martin et al. (2007) *J. Biosci.* 32:1049-1052 at page 1049, 4th full paragraph.

d. Martin et al. (2007) *J. Biosci.* 32:1049-1052, reviewing the state of the art of miRNA prediction programs, state mammalian miRNA targets are considered

difficult to predict because miRNA targets display only partial complementarity to the mature miRNA sequence (pg. 1049). Martin et al. further state that "Given the high level of both false-positives and false-negatives resulting from the application of current miRNA target prediction programs, it is clear that experimental testing of predicted miRNA targets is critically important in order to validate/confirm any putative miRNA-target gene combination" (pg. 1050, 4th complete paragraph). Martin et al. further teach that miRNA prediction programs rely on sequence, structure, and evolutionary conservation information to predict genes likely to be targeted by miRNAs, but that the requirement for conserved sites means that non-conserved sites, which may represent real targets, are completely missed.

e. Maziere et al. (2007) *Drug Discovery Today* 12:452-458, in their article entitled "Prediction of miRNA Targets," state that it is difficult to estimate the true false positive/negative rates of miRNA prediction programs because few validated miRNA targets are known (page 457), and, that comparison of miRNA prediction efficiencies among different programs is not currently possible because many of the programs are not available for download and use on a common dataset.

f. Smalheiser et al. (2006) *Methods Mol. Biol.* 342:115-127 in an article entitled "Complications in miRNA Target Prediction" state that complementarity between miRNAs and their targets is not the only factor that may govern which miRNA-mRNA target interactions are effective in vivo. One must

consider the potential importance of mRNA target secondary structure, as well as the strong possibility that RNA-binding proteins may participate in miRNA recognition. Furthermore, both miRNA and mRNA need to be coexpressed in proper amounts within the cell for effective interaction to occur, and A-to-I editing of RNA might abrogate potential mRNA targets from being effectively silenced by the RNA-induced silencing complex (page 124). Smalheiser et al. further teach that not all mammalian miRNAs interact with their targets via "short seeds," complementary regions of 6-8 nucleotides, but, instead, may interact via "long" seeds and perfect matches (page 115-6), and because new miRNAs are constantly being discovered this list of binding determinants may not be complete.

g. Lagos-Quintana (2001) "Identification of novel genes coding for small expressed RNAs" *Science* 294:853-858 taught that despite advanced genome projectes, computer-assisted detection of genes encoding functional RNAs remains problematic (page 9 bridging to 10). It is said that because the interaction between an miRNA and its target is only 6-10 bases pairs long and often contains bulges and G/U wobbles, the prediction of miRNA target mRNAs represents a challenging bioinformatic and/or genetic task (page 10).

5. No evidence is found in the instant application or prior art directly comparing the output of the instant algorithm with the other cited programs when presented with a common dataset. No supporting data or similar evidence or information is found regarding the accuracy or false positive rate of the instant algorithm used to predict

the instantly claimed sequences. Thus, there is no objective evidence to evaluate the accuracy or reliability of the algorithm used by Applicant to predict miRNAs or their function.

6. Accordingly, while the ability to predict hairpin-like structures and potential gene targets from genomic sequence information appears to be within the state of the art, the art teaches that validating the true biological function of any predicted miRNA sequence requires analyzing miRNA expression patterns, as well as testing the effects of miRNA overexpression and underexpression under different conditions in living cells *in vitro* and *in vivo*. While these methods, too, are within the level of skill in the art, Applicant has presented no evidence that any of these validation techniques have, in fact, been carried out with regard to the instantly claimed sequences. As a result, one of skill would be left to de novo screening testing to identify such function, with no assurance that any practical or beneficial function would ever be identified.

Altogether, then, there is substantial evidence to indicate that, at the time of filing, one of skill would have had reason to doubt the objective truth of the alleged utility of a bioinformatically predicted miRNA, given the proposed target was bioinformatically predicted, the accuracy and/or false positive rate of the bioinformatic prediction method was and remains unknown, and given that no experimental data is available to confirm the predicted activity.

There is no evidence in the prior art or application to show that each and every (or at least the majority of) miRNA-like hairpin predicted by the instant algorithm in fact regulates expression of a gene. Indeed, miRNA-like, non-translated hairpin RNAs may have any

number of different biological activities in the cell, known or yet-to-be discovered. The assertion that each miRNA inhibits the expression of at least one gene is an assumption based on past findings with other miRNAs, and does not account for potential additional or unrelated activities.

Even more, Applicant seeks to claim not only the specified sequences, but RNA equivalents, complements, and all sequences 80% identical to SEQ ID NO:159 and 6821380 and equivalents thereto. No evidence is remotely evident suggesting a substantial utility for all these sequences. The claims are extremely broad, encompassing an enormous number of different sequences that could produce any number of different biological effects.

No evidence is found suggesting or stating that SEQ ID NO:159 or 6821380 has been made, isolated, cloned, detected, expressed, or even analyzed in a living cell *in vitro* or *in vivo*. In summary, no biological or biochemical function has been assigned to the instant sequences apart from the general assertions that they, like the thousands of other sequences described in the sequence listing, may correspond to an miRNA precursor or mature counterpart and have some direct or indirect relation to gene expression and disease.

Thus, the proposed utilities of the instantly claimed nucleic acids as a therapeutic target or agent, or material resource for preparing diagnostic probes, inhibitory agents, vectors, and host cells, are simply starting points for further research and investigation into potential practical uses of the claimed polynucleotides. If no specific or substant utility is found for the miRNA-like sequence themselves, no practical or real world value is provided by the complements or vectors thereto.

Brenner v. Manson, 148 U.S.P.Q. 689 (U.S. 1966)

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.
>
> …a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

In summary, the instant application claims bioinformatically predicted preprocessed and mature miRNA sequences corresponding to SEQ ID NO:6821380 and 159, respectively. Specific and substantial utility is thereby asserted based on bioinformatic data (although the specific target is currently unclear). The asserted utility has not been experimentally verified. Indeed, there is no experimental evidence of even a single biological function. Function is asserted solely on the basis of a computer program designed to predict miRNA-like hairpin sequences and mature miRNAs derived therefrom by Dicer-catalyzed processing, which information is mined from raw genomic sequences.

At issue, then, is whether one of skill would more likely than not believe the nucleic acids predicted by Applicant's algorithm, such as the sequences now claimed, would have the specific and substantial utility predicted by the program. (At present, the specific and substantial utility remains unclear.) The answer lies in the predictive quality of the program used to identify the miRNAs and their target sites. A quantifiable value is not readily apparent to the Examiner from the facts of record. Indeed, the Examiner is unable to find any disclosure by the inventor either in the instant application or in the pre- or post-filing art clearly articulating the sensitivity or false positive rate of the instant algorithm. A simple statement supported by actual experimental evidence, showing the algorithm correctly predicts an miRNA and its activity more than half of

the time and has an acceptable false positive rate would be sufficient to overcome the instant rejection. Currently, however, the specification does not address this question directly or completely. Accuracy would depend on several factors, including but not limited to the accuracy of the HAIRPIN DETECTOR and the accuracy of the DICER-CUT LOCATION DETECTOR. It would appear from the teachings in the specification that multiple determinants govern the selection process.

Thus, multiple factors are involved in miRNA-target binding and recognition. Thus, in view of the totality of the evidence, one of skill would have reason to doubt the objective truth of the asserted utility. While the instant algorithm provides a list of putative miRNAs and corresponding target sites, there is reason to question whether the bioinformatic algorithm used to produce this list correctly identifies an miRNA and its function (i.e., at least one biological function) with minimally acceptable false positive and false negative rates such that one of skill would believe the miRNA would, more likely than not, inhibit the gene predicted by the software. Without experimental validation or any verifiable evidence of the accuracy and error rates of the instant program, and in view of the state of the art at the time of invention, one of skill would reasonably question the certainty of the prediction at the time of filing. The skilled artisan would be led to believe only that the instantly claimed nucleic acids require further research to verify the asserted utility.

Thus, the specification does not teach a specific, substantial, or credible utility for SEQ ID NO:159 or 6821380, much less any of the RNA equivalents or complements thereof. No target gene has been conclusively identified nor has any evidence been presented linking the claimed nucleic acids with any target gene, disease, or condition, biological function or disorder.

A substantial nexus has not been established. Finally, even if a specific and substantial utility were found or pointed to by applicant (as by providing a copy of the portion of the mega table disclosing the asserted utility), there is substantial evidence to doubt the objective truth of the asserted utility in view of the unpredictability in the art of miRNA prediction by bioinformatic analysis.

***

Claims 25, 26, 29, 30, and 35-38 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Examiner, AU1635
September 3, 2008